

**UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF ILLINOIS**

LUCINDA O'DEA, individually and on  
behalf of all others similarly situated,

Plaintiff,

v.

RB HEALTH (US) LLC,

Defendant.

Case No.

**CLASS ACTION COMPLAINT**

**JURY TRIAL DEMANDED**

**CLASS ACTION COMPLAINT**

Plaintiff Lucinda O'Dea ("Plaintiff"), by and through her attorneys, makes the following allegations pursuant to the investigation of her counsel and based upon information and belief, except as to allegations specifically pertaining to herself, which are based on personal knowledge, against Defendant RB Health (US) LLC ("RB Health" or "Defendant").

**NATURE OF THE ACTION**

1. This is a class action lawsuit regarding Defendant's manufacturing, distribution, advertising, marketing and sale of acne treatment products under various brands that contain the active ingredient benzoyl peroxide ("BPO") (the "Products"). BPO degrades over time into benzene, a carcinogenic impurity that has been linked to leukemia and other cancers.

2. These Products are not designed to contain benzene, and the use of benzene in the manufacturing process is not "unavoidable." Thus, the presence of benzene in the Products renders them adulterated and misbranded, and therefore illegal to sell under both federal and state law. As a result, the Products are unsafe and illegal to sell under federal law, and therefore

worthless. *See* 21 U.S.C. §§ 331(a), 352; *see also Barnes v. Unilever United States Inc.*, 2022 WL 2915629, at \*1-3 (N.D. Ill. July 24, 2022); *Debernardis v. IQ Formulations, LLC*, 942 F.3d 1076, 1085 (11th Cir. 2019); *In re Valsartan, Losartan, & Irbesartan Prod. Liab. Litig.*, 2021 WL 222776, at \*16 (D.N.J. Jan. 22, 2021).

3. The benzene present in the Products is present in the finished Product because the Product is formulated with benzoyl peroxide (“BPO”), that degrades over time, directly into the human carcinogen benzene.

4. Although Defendant lists both active and inactive ingredients on the Products’ labels, benzene is not among those ingredients listed. Thus, Defendant misrepresents that the Products do not contain benzene, or otherwise Defendant fails to disclose that the Products contain benzene. Plaintiff and other Class Members would not have purchased the Products, or would have paid substantially less for the Products, had Defendant disclosed that the Products contained or risked containing benzene, or otherwise not misrepresented that the Products did not contain or were not at risk of containing benzene.

5. Defendant failed to detect or prevent the benzene in its Products, and Plaintiff and consumers were harmed as a result of Defendant’s failure.

6. Defendant represents that the Products are safe for their intended use. But the Products actually contain benzene at the time of purchase, and prospective consumers are unaware of this fact because the chemical is not included on the Products’ ingredients list or packaging.

7. Further, Plaintiff and Class Members reasonably relied on Defendant’s representations that the Products were safe, unadulterated, and free of any carcinogens that are not listed on the label.

8. Plaintiff and Class Members purchased and used the Product and were therefore exposed to or risked being exposed to the harmful presence of benzene in the Products.

9. The Product is worthless because it contains or risked containing benzene, a known human carcinogen that is an avoidable ingredient in the Product and their manufacturing process. Indeed, the presence of benzene renders the Product adulterated, misbranded, and illegal to sell.

10. Defendant failed to test for, detect, or prevent the benzene contamination in its Product, and Plaintiff and consumers were harmed as a result of Defendant's failure.

11. Feasible alternative formulations, designs and materials, such as including antioxidants, were available to Defendant at the time the Product was formulated designed, and manufactured, to prevent and/or inhibit the formation of benzene in the Products.

12. Defendant is therefore liable to Plaintiff and Class Members for selling the Product because (i) Defendant represented the Product did not contain benzene and/or failed to disclose the presence of benzene in the Product, and Plaintiff and Class Members would not have purchased the Products or would have paid less for the Products had they known the Product contained or risked containing benzene, and (ii) the Product were adulterated, misbranded, and illegal to sell due to the presence of benzene, and therefore worthless.

13. Defendant did not disclose the actual or potential presence of benzene in its Products' labeling, advertising, marketing, or sale.

## **PARTIES**

### **I. Plaintiff**

14. Plaintiff Lucinda O'Dea is a resident and citizen of Berwyn, Illinois. Approximately three years ago, Plaintiff purchased and used RB Health's Clearasil 10% BPO cream from a CVS store in Chicago, Illinois.

15. When purchasing the Product, Plaintiff reviewed the accompanying labels and disclosures, and understood them as representations and warranties by Defendant that the Product was properly manufactured, free from defects, safe for its intended use, not adulterated or misbranded, and legal to sell. The Product likewise contained no representation that it contained

or risked containing benzene. Plaintiff relied on these representations and warranties in deciding to purchase the Product manufactured and sold by Defendant, and these representations and warranties were part of the basis of the bargain, in that she would not have purchased the Product from Defendant if she had known that they were not, in fact, properly manufactured, free from defects, safe for their intended use, not adulterated and misbranded, and legal to sell. The Product Plaintiff purchased was worthless because it either contained or risked containing the known carcinogen benzene. Accordingly, the Plaintiff was injured in fact and lost money as a result of Defendant's deceptive and unfair conduct.

16. Plaintiff would be willing to purchase the Product again, provided that she could be ensured that Defendant does not omit the presence of benzene in the Product and that the Product does not contain benzene.

## **II. Defendant**

17. Defendant RB Health (US) LLC is a Delaware corporation with its principal place of business and headquarters located at 399 Interpace Parkway, Parsippany, NJ.

18. Defendant sells the Products throughout the United States, including in the State of Illinois. The Products, including those purchased by Plaintiff and Class Members, are available at various retail stores throughout the United States, including in the State of Illinois.

19. Defendant authorized the false, misleading, and deceptive marketing, advertising, distribution, and sale of the Products.

## **JURISDICTION AND VENUE**

20. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(d)(2)(A), as modified by the Class Action Fairness Act of 2005, because at least one member of the Class, as defined below, is a citizen of a different state than Defendant, there are more than 100 members of the Class, and the aggregate amount in controversy exceeds \$5,000,000 exclusive

of interest and costs.

21. This Court has personal jurisdiction over Defendant because this action arises out of and relates to Defendant's contacts with this forum. Specifically, Defendant knowingly placed the Product into the stream of commerce directed into this District. Defendant has advertised and marketed within this District through the wires and mail and via e-commerce websites through which residents of this state and District can purchase the Product. Further, Defendant knowingly directs electronic activity into this state and District with the intent to engage in business interactions and has in fact engaged in such interactions. Moreover, Defendant makes the Product available at retailers throughout this District.

22. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b) because a substantial part of the events or omissions giving rise to the claim occurred within this District, Defendant has caused harm to Plaintiff and other Class members in this District, and otherwise has purposefully availed itself of the markets in this District, through the promotion, sale, and marketing of the Products in this District.

### **FACTUAL ALLEGATIONS**

#### **I. Defendant's Background**

23. Defendant owns Clearasil. Clearasil specializes in skincare products, including facial scrubs and washes, creams and lotions, and toners. Clearasil's products treat conditions like acne and breakouts.

24. Clearasil markets and sells BPO-containing acne treatment products as part of its Acne Spot Treatment products line.



<p>CLEARASIL® RAPID RESCUE SPOT TREATMENT CREAM</p> <p>When treating pimples, faster is better. Spot Treatment Cream visibly reduces redness and pimple size in as fast as 4 hours! Dermatologist tested, it starts to work instantly, opens up blocked pores and delivers maximum strength active deep into the pores. Apply on the spot as and when needed.</p>	
<b>Drug Facts</b>	
<b>Active ingredient</b>	<b>Purpose</b>
Benzoyl peroxide 10%.....	Acne medication
<b>Use</b> for the treatment of acne	
<b>Warnings</b>	
For external use only	
Do not use if you	
<ul style="list-style-type: none"> <li>have very sensitive skin</li> <li>are sensitive to benzoyl peroxide</li> </ul>	
<b>When using this product</b>	
<ul style="list-style-type: none"> <li>avoid unnecessary sun exposure and use a sunscreen</li> <li>avoid contact with the eyes, lips and mouth</li> <li>avoid contact with hair and dyed fabrics, including carpet and clothing, which may be bleached by this product</li> <li>skin irritation and dryness is more likely to occur if you use another topical acne medication at the same time. If irritation occurs, only use one topical acne medication at a time.</li> <li>skin irritation may occur, characterized by redness, burning, itching, peeling or possibly swelling. Irritation may be reduced by using the product less frequently or in a lower concentration.</li> </ul>	
<b>Stop use and ask a doctor</b> if irritation becomes severe.	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center immediately.	

## **II. Benzene Is a Known Human Carcinogen**

25. A study from 1939 on benzene stated that “exposure over a long period of time to any concentration of benzene greater than zero is not safe,”<sup>1</sup> which is a comment reiterated in a 2010 review of benzene research specifically stating: “There is probably no safe level of exposure to benzene, and all exposures constitute some risk in a linear, if not supralinear, and additive fashion.”<sup>2</sup>

26. Benzene is a component of crude oil, gasoline, and cigarette smoke, and is one of the elementary petrochemicals. The Department of Health and Human Services has determined that benzene causes cancer in humans. Likewise, the Food and Drug Administration (“FDA”) lists benzene as a “Class 1 solvent” that “should not be employed in the manufacture of drug substances, excipients, and drug products because of [its] unacceptable toxicity.” Benzene is associated with blood cancers such as leukemia.<sup>3</sup>

27. The CDC warns that “[b]enzene works by causing cells not to work correctly. For example, it can cause bone marrow not to produce enough red blood cells, which can lead to anemia. Also, it can damage the immune system by changing blood levels of antibodies and causing the loss of white blood cells.” The CDC also cautions that “[d]irect exposure of the eyes, skin, or lungs to benzene can cause tissue injury and irritation.”<sup>4</sup>

28. According to the National Institute for Occupational Safety and Health, humans can become exposed to benzene through “inhalation, skin absorption, ingestion, skin and/or eye

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<sup>1</sup> F.T. Hunter, *Chronic Exposure to Benzene (Benzol). II. The Clinical Effects*, 21 JOURNAL OF INDUSTRIAL HYGIENE AND TOXICOLOGY 331 (1939), <https://www.cabdirect.org/cabdirect/abstract/19402700388>.

<sup>2</sup> Martyn T. Smith, *Advances in Understanding Benzene Health Effects and Susceptibility*, 31 ANNUAL REVIEW OF PUBLIC HEALTH 133 (2010), <https://www.annualreviews.org/doi/full/>

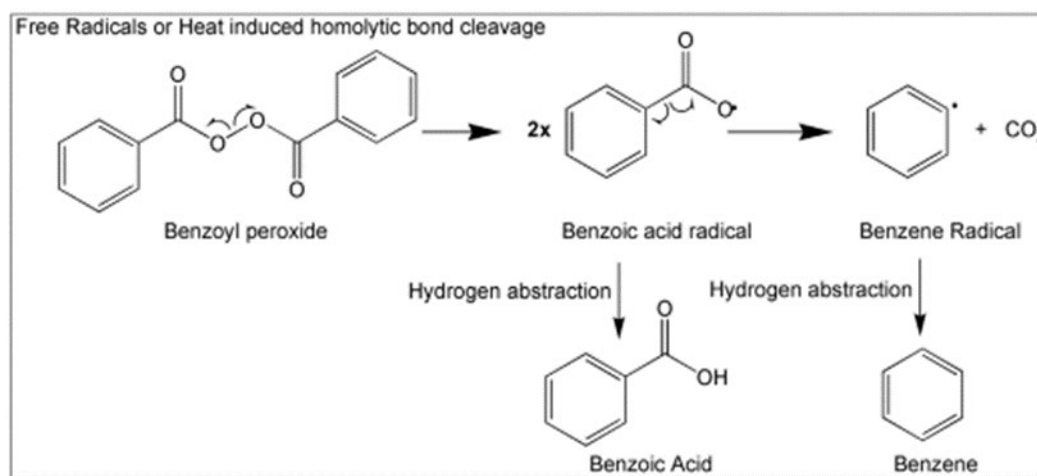
<sup>3</sup> National Cancer Institute, Cancer-Causing Substances, Benzene, <https://www.cancer.gov/about-cancer/causes-prevention/risk/substances/benzene>

<sup>4</sup> Centers for Disease Control and Prevention, Facts About Benzene, <https://emergency.cdc.gov/agent/benzene/basics/facts.asp>.

contact.”<sup>5</sup>

### III. BPO Is Unstable And Degrades into Benzene

29. The drug benzoyl peroxide (“BPO”) is a diacyl peroxide with bacterial activity and is widely used as a treatment for acne. The Products made by Defendant contain BPO and the BPO degrades over time to directly form Benzene.<sup>6</sup>



30. The benzene created in the Product is a result of Benzoyl peroxide is known to thermally decompose to form two molecules of benzoic acid radicals that can further decompose to benzene radicals with liberation of carbon dioxide. The benzene radicals can then produce benzene.<sup>7</sup> This process is often accelerated by exposure to elevated temperatures equivalent to a hot bathrooms or the temperature of a hot car/truck/shipping container, which associated with the transportation of goods. Accordingly, the creation of benzene in the Product is a natural and foreseeable result of the Product’s distribution and handling, and is be common to all consumers.

31. The instability of benzoyl peroxide and its degradation into benzene has been

<sup>5</sup> National Institute for Occupational Safety and Health (NIOSH), Benzene, <https://www.cdc.gov/niosh/npg/npgd0049.html> (emphasis added).

<sup>6</sup> See <https://www.valisure.com/valisure-newsroom/valisure-detects-benzene-in-benzoyl-peroxide> (last visited March 8, 2024).

<sup>7</sup> Id.



studied in other applications, including in the polymer industry. Studies dated as early as 1994 have noted the connection between benzoyl peroxide and benzene. For the same reasons, various methods have been developed to reduce the degradation of benzoyl peroxide into benzene in these applications. For example, some antioxidants have been shown to reduce benzene formation by 98 percent.

32. On information and belief, Defendant was aware of the degradation issues associated with benzoyl peroxide. The harms associated benzoyl peroxide were known within scientific literature and was likely disclosed to Defendant when it sourced its benzoyl peroxide. Any reasonable drug manufacturer would have discovered these issues during product development and sourcing of the ingredients.

33. Nonetheless, Defendant did nothing to mitigate both the possibility of and the harms associated with the degradation of benzoyl peroxide into benzene. Additionally, Defendant did not warn consumers regarding the risk of benzene or provide handling instructions to limit benzoyl peroxide degradation.

#### **IV. Exposure to Benzene in any Amount Is Extremely Dangerous**

34. The harm associated with benzene contamination in drugs is significant. Benzene is a component of crude oil, gasoline, and cigarette smoke, and is one of the elementary petrochemicals.<sup>8</sup> The FDA currently recognizes the danger of benzene and, as a result, has claimed it should not be used in the manufacture of any component of a drug product due to its unacceptable toxicity effect.<sup>9</sup>

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<sup>8</sup> Benzene, National Cancer Institute, <https://www.cancer.gov/about-cancer/causes-prevention/risk/substances/benzene> (last updated Dec. 5, 2022).

<sup>9</sup> David Light et al., Valisure Citizen Petition on Benzene in Body Spray Products (Nov. 3, 2021), [https://assets-global.website-files.com/6215052733f8bb8fea016220/626af96f521a0584e70e50eb\\_Valisure%20FDA%20Citizen%20Petition%20on%20Body%20Spray%20v4.0%5B260%5D.pdf](https://assets-global.website-files.com/6215052733f8bb8fea016220/626af96f521a0584e70e50eb_Valisure%20FDA%20Citizen%20Petition%20on%20Body%20Spray%20v4.0%5B260%5D.pdf) (the “Valisure Citizen Petition”).

35. Where the use of benzene or other Class 1 solvents is *unavoidable*, the FDA has stated that the levels should be restricted, and benzene is restricted under such guidance to 2 parts per million (“ppm”).<sup>10</sup>

36. A 2010 study summarized the epidemiological studies of the carcinogenic effects of benzene exposure and provided an overview of the hematotoxic effects of benzene.<sup>11</sup> The study concluded:

- (a) There is probably no safe level of exposure to benzene, and all exposures constitute some risk in a linear, if not supralinear, and additive fashion.
- (b) Exposure to benzene can lead to multiple alterations that contribute to the leukemogenic process, indicating a multimodal mechanism of action.
- (c) Benzene is a ubiquitous chemical in our environment that causes acute leukemia and probably other hematological cancers.

37. The CDC has stated that ways in which people “could be exposed to benzene” include:<sup>12</sup>

- (a) Outdoor air contains low levels of benzene from tobacco smoke, gas stations, motor vehicle exhaust, and industrial emissions.
- (b) Indoor air generally contains levels of benzene higher than those in outdoor air. The benzene in indoor air comes from products that contain benzene such as glues, paints, furniture wax, and detergents.
- (c) The air around hazardous waste sites or gas stations can contain higher levels of benzene than in other areas.

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<sup>10</sup> Id.

<sup>11</sup> F.T. Hunter, Chronic Exposure to Benzene (Benzol): The Clinical Effects, 21 J. Indus. Hygiene & Toxicology 331 (1939), <https://www.cabdirect.org/cabdirect/abstract/19402700388>.

<sup>12</sup> *Facts About Benzene*, CDC (last updated Apr. 4, 2018) <https://emergency.cdc.gov/agent/benzene/basics/facts.asp>.

- (d) Benzene leaks from underground storage tanks or from hazardous waste sites containing benzene can contaminate well water.
- (e) People working in industries that make or use benzene may be exposed to the highest levels of it.
- (f) A major source of benzene exposure is tobacco smoke.

38. The NIOSH and CDC identify “exposure routes” for benzene to include: “inhalation, skin absorption, ingestion, skin and/or eye contact.”<sup>13</sup>

39. “Direct exposure [to benzene] of the eyes, skin, or lungs to benzene can cause tissue injury and irritation.”<sup>14</sup>

40. Skin absorption is particularly concerning as there have been multiple FDA studies showing that structurally similar chemicals in sunscreen products are found in the blood at high levels after application to exposed skin.

41. Benzene exposure from acne creams and gels are especially troubling because the creams and gels are applied directly onto the skin. Thus, even a relatively low concentration limit can result in very high total benzene exposure.

## **V. Discovery of Benzene**

42. Valisure LLC is an analytical laboratory and an online pharmacy known for its rigorous testing of medications and healthcare products to ensure their safety, quality, and consistency. Valisure is “accredited to International Organization for Standardization (“ISO/IEC”) 17025:2017 standards for chemical testing (PJLA Accreditation Number 94238) [and] registered with the Drug Enforcement Administration (License # RV0484814).” Its core mission is “to help

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<sup>13</sup> NIOSH Pocket Guide to Chemical Hazards: Benzene, CDC, <https://www.cdc.gov/niosh/npg/npgd0049.html> (last updated Oct. 30, 2019).

<sup>14</sup> *Facts About Benzene*, *supra*.

ensure the safety, quality and consistency of medications and supplements in the market.”

43. On March 6, 2024, Valisure announced Benzoyl peroxide acne treatment products are unstable and form benzene.<sup>15</sup>

44. Results from Valisure’s tests show that on-market BPO products can form over 800 times the conditionally restricted FDA concentration limit of 2 parts per million (ppm) for benzene, and the current evidence suggests that this problem applies broadly to BPO products currently on the market. High levels of benzene were not only detected inside BPO products, but also in the air around incubated BPO products, showing that benzene can leak out of some product packages and pose a potential inhalation risk. Incubation of a Proactiv® product at the temperature of a hot car (70°C) resulted in the detection of benzene in a compact car’s volume of air at ~1,270 times the Environmental Protection Agency’s (“EPA”) calculated threshold for increased cancer risk by long-term inhalation exposure to benzene.

45. David Light, Valisure’s Co-Founder and President stated: “This discovery of benzoyl peroxide’s fundamental instability and formation of benzene is substantially different than Valisure’s previous findings of benzene in sunscreens, hand sanitizers and other consumer products. The benzene we found in sunscreens and other consumer products were impurities that came from contaminated ingredients; however, the benzene in benzoyl peroxide products is coming from the benzoyl peroxide itself, sometimes at hundreds of times the conditional FDA limit. This means the problem broadly affects benzoyl peroxide products, both prescription and over-the-counter, and necessitates urgent action.”<sup>16</sup>

46. Valisure performed initial GC-MS analysis on 175 acne treatment products, 99

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<sup>15</sup> <https://www.valisure.com/valisure-newsroom/valisure-detects-benzene-in-benzoyl-peroxide> (last visited April 1, 2024).

<sup>16</sup> *Id.*

containing BPO and 76 containing other ingredients, most commonly salicylic acid or adapalene. All 76 non-BPO products had no detectable benzene or values below 2 ppm, and 94 of 99 BPO products contained benzene without any elevated temperature incubation. An initial stability study of 5 products using 37°C, 50°C and 70°C revealed that dozens of ppm of benzene can form in just a few weeks at 37°C, hundreds of ppm at 50°C, and at 70°C the apparent degradation of BPO would often lead product packaging to burst. Therefore, 50°C was chosen as a stability temperature for a broader study of 66 BPO containing products. In 18 days of stability testing at 50°C, Valisure detected over 1,500 ppm of benzene produced in 2 products, over 100 ppm in 17 products, and over 10 ppm in 42 products.

47. The Valisure study found unacceptable levels of benzene in Defendant's Clearasil 10% BPO cream.<sup>17</sup>

48. The Valisure study also noted that **“the specific problem with benzene in benzoyl peroxide products does not appear to be a contamination issue from a specific ingredient, but instead the inherent instability of the benzoyl peroxide molecule that breaks down and forms benzene.”**<sup>18</sup>

## VI. Defendant does not Disclose that the Products Contain Benzene

49. Defendant's products should not have contained Benzene. Further, although Defendant lists the ingredients on each of the Products' labels, Defendant failed to disclosure on the Products' labeling or anywhere in its marketing that the Products contain or risked containing benzene.

<sup>17</sup> See <https://www.dermatologytimes.com/view/breaking-news-benzene-found-in-various-acne-products-valisure-files-petition-with-fda-to-recall-treatments> (last visited April 1, 2024).

<sup>18</sup> VALISURE CITIZEN PETITION ON BENZENE IN BENZOYL PEROXIDE DRUG PRODUCTS, at 8, [https://assets-global.website-files.com/6215052733f8bb8fea016220/65e8560962ed23f744902a7b\\_Valisure%20Citizen%20Petition%20on%20Benzene%20in%20Benzoyl%20Peroxide%20Drug%20Products.pdf](https://assets-global.website-files.com/6215052733f8bb8fea016220/65e8560962ed23f744902a7b_Valisure%20Citizen%20Petition%20on%20Benzene%20in%20Benzoyl%20Peroxide%20Drug%20Products.pdf) (emphasis in original).

50. For each of the Products, Defendant made a partial representation, by disclosing some of the ingredients within the Products, but by omitting the presence of benzene. This would lead a reasonable consumer to believe that Defendant had disclosed all the material ingredients within the Products, and that the Product did not contain any other material ingredients.

51. Here, the misrepresentation of the ingredients within the Products, and the omission of the risk of the Products containing benzene, directly relates to the safety of the Product.

52. Any reasonable consumer would find the presence of dangerous substances, such as benzene, material in a drug product. Indeed, had the presence of benzene been disclosed by Defendant, the product would not have likely been on the shelves. Accordingly, Plaintiff and other consumers would not have purchased the Products, had the truth of the benzene within the Products been known or, at least, paid less.

## **VII. Benzene Renders the Products Adulterated, Misbranded, and Illegal to Sell**

53. Acne treatment products are “drug” products that are regulated by the U.S. Food and Drug Administration (“FDA”),<sup>19</sup> pursuant to the federal Food, Drug and Cosmetics Act (“FDCA”), 21 U.S.C. § 301 *et seq.*, as well as analogous state statutes and regulations.

54. As OTC drug products regulated by the FDA, the Products must be both safe and effective and are subject to federal current Good Manufacturing Practices (“cGMP”) regulations and the FDCA’s state law analogues. These cGMP regulations require OTC medications like the Products to meet safety, quality, purity, identity, and strength standards. *See* 21 U.S.C. § 351(a)(2)(B).

55. The cGMPs establish “minimum current good manufacturing practice for methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or

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<sup>19</sup> See VALISURE CITIZEN PETITION ON BENZENE IN BENZOYL PEROXIDE DRUG PRODUCTS, at 3.

holding of a drug to assure that such drug meets the requirements of the act as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess.” 21 C.F.R. § 210.1(a). In other words, manufacturers, like Defendant, at all phases of the design, manufacture, and distribution chain are bound by these requirements.

56. The cGMPs set forth minimum standards regarding: organization and personnel (Subpart B); buildings and facilities (Subpart C); equipment (Subpart D); control of components and drug product containers and closures (Subpart E); production and process controls (Subpart F); packaging and label controls (Subpart G); holding and distribution (Subpart H); laboratory controls (Subpart I); records and reports (Subpart J); and returned and salvaged drug products (Subpart K). The FDA has worldwide jurisdiction to enforce these regulations if the facility is making drugs intended to be distributed in the United States.

57. Any drug product not manufactured in accordance with cGMPs is deemed “adulterated” or “misbranded” and may not be distributed or sold in the United States. *See* 21 U.S.C. §§ 331(a), 351(a)(2)(B). States have enacted laws adopting or mirroring these federal standards.

58. FDA regulations require a drug product manufacturer to have “written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.” 21 C.F.R. § 211.100.

59. A drug product manufacturer’s “[l]aboratory controls shall include the establishment of scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components, drug product containers, closures, in-process materials, labeling, and drug products conform to appropriate standards of identity, strength, quality, and purity.” 21 C.F.R. § 211.160.

60. “Laboratory records shall include complete data derived from all tests necessary to assure compliance with established specifications and standards, including examinations and assays” and a “statement of the results of tests and how the results compare with established standards of identity, strength, quality, and purity for the component, drug product container, closure, in-process material, or drug product tested.” 21 C.F.R. § 211.194(a)(6).

61. FDA guidance permits up to 2 ppm benzene in a product if its use in the manufacturing process is “unavoidable.”<sup>20</sup>

62. Given the long history and widespread use of acne products without any benzene contamination, the use of benzene in the Products is not “unavoidable,” and *any* level of benzene in the Products is therefore unacceptable.

63. But regardless, Defendant’s Products likely contain levels of benzene above 2 ppm.

64. Defendant also could have avoided any potential for benzene contamination in the Products by changing the manufacturing process or raw ingredients, and the Products could have been sold with absolutely no benzene in them.

65. The mere presence of benzene—which, upon information and belief, resulted from Defendant’s failure to comply with cGMPs—renders the Products both adulterated and misbranded under the FDCA. The Products are adulterated because they are “drug[s] and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess.” 21 U.S.C. § 351(a)(1).

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<sup>20</sup> *Valisure Citizen Petition, supra*.



66. The Products are misbranded because their labeling is “false” and “misleading” because it does not disclose the presence of benzene. 21 U.S.C. § 352(a)(1).

67. A product that is “adulterated” or “misbranded” cannot legally be manufactured, advertised, distributed, or sold. 21 U.S.C. § 331(a). Adulterated and misbranded products thus have no economic value and are legally worthless.

68. The Illinois Food, Drug and Cosmetic Act (“IL FDCA”) has expressly adopted the federal labeling requirements as its own. The definition of “adulterated” as defined by 410 ILCS 620/14 is exactly the same as the FD&C Act.

69. As alleged herein, Defendant has violated the FDCA, the IL FDCA, and the Illinois Consumer Fraud and Deceptive Trade Practices Act (“ICFA”). Defendant engaged in fraudulent, unfair, deceptive, misleading, and/or unlawful conduct stemming from its misrepresentations and omissions surrounding benzene contamination affecting the Products.

70. If Defendant had disclosed to Plaintiff and putative Class Members that the Products contained or risked containing benzene and thus risked users to benzene exposure, Plaintiff and putative Class Members would not have purchased the Products or they would have paid less for the Products.

71. As a seller of an OTC drug product, Defendant had and has a duty to ensure that its Products did not and do not contain excessive (or any) level of benzene, including through regular testing, especially before injecting the Products into the stream of commerce for consumers to use on their bodies. But based on Valisure’s testing results, Defendant made no reasonable effort to test its Products for benzene or other impurities. Nor did it disclose to Plaintiff in any advertising or marketing that its acne products contained benzene, let alone at levels that are above the emergency, interim limit set by the FDA. To the contrary, Defendant represented that the Products

were of merchantable quality, complied with federal and state law, and did not contain carcinogens or other impurities such as benzene.

**VIII. Defendant's Knowledge, Misrepresentations, Omissions, and Concealment of Material Facts Deceived Plaintiff and Reasonable Consumers**

72. The Products contain Benzoyl Peroxide (BPO), which Defendant identified in the ingredient list of the Products.

73. Because BPO is known to decompose thermally into benzoic acid radicals, which can further decompose into benzene radicals, eventually leading to the production of benzene, there is high potential for benzene in the Products containing BPO.

74. Defendant, a large, sophisticated corporation of pharmaceutical drugs, knew or should have known of the risks of benzene being present in the Products.

75. Defendant sold acne cream and gel products containing benzene during the class period despite Defendant's knowledge of the risk of benzene.

76. Benzene is not listed on the Products' labels as an ingredient, nor is there any warning about the inclusion (or even potential inclusion) of benzene in the Products.

77. Defendant made all of these assurances regarding the safety and quality of its Products despite the fact that it was selling adulterated, misbranded, and therefore illegally sold and worthless Products to consumers.

78. Further, Defendant made all of these assurances regarding the safety and quality of its Products without disclosing to consumers that its Products contained cancer-causing chemical (benzene). This is misleading to consumers.

79. Moreover, Plaintiff and the putative Class members were exposed to one or more of these representations during the class period and relied on one or more of these representations in deciding to purchase Defendant's Products. In addition, although the Products were found to

contain benzene, Defendant does not list benzene among the ingredients anywhere on its website, and nothing on the Products' labels otherwise insinuate, state, or warn that the Products contain benzene. Again, such misrepresentations mislead consumers regarding the safety and quality of the Products.

80. As such, Defendant's advertising campaigns are false and misleading. Plaintiff would not have purchased the Products had they been truthfully and accurately labeled.

81. The presence of benzene in the Products also renders the Products misbranded and adulterated and therefore illegal and unfit for sale in trade or commerce.

82. If Defendant had fulfilled their quality assurance obligations, Defendant would have identified the presence of benzene through routine and required testing.

83. Further, had Defendant adequately tested its Products for benzene and other carcinogens and impurities, it would have discovered that its Products contained benzene—even at levels above the FDA's limit (to the extent even applicable)—making those Products illegal to distribute, market, and sell.

84. Defendant also knew or should have known about the carcinogenic potential of benzene because it is classified as a Group 1 compound by the World Health Organization and the International Agency for Research on Cancer, meaning that it is "carcinogenic to humans."<sup>21</sup>

85. Accordingly, Defendant knowingly, recklessly, or at least negligently, introduced contaminated, adulterated, and misbranded Products containing or risked containing dangerous amounts of benzene into the U.S. market.

86. By marketing and selling its acne products in the stream of commerce with the intent that its Products would be purchased by Plaintiff and Class Members, Defendant warrants

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<sup>21</sup> [https://monographs.iarc.who.int/wp-content/uploads/2019/07/Classifications\\_by\\_cancer\\_site.pdf](https://monographs.iarc.who.int/wp-content/uploads/2019/07/Classifications_by_cancer_site.pdf).

that the Products are safe to use rather than adulterated acne creams containing a dangerous, cancer-causing chemical.

87. Defendant did not disclose the actual or potential presence of benzene in its acne products on the Products' labeling, advertising, marketing, or sale of the Products.

88. Defendant's concealment was material and intentional because people are concerned with what is in the products that they are putting onto and into their bodies. Consumers such as Plaintiff and Class Members make purchasing decisions based on the representations made on the Products' labeling, including the ingredients listed.

89. Defendant knows that if it had not misrepresented or omitted that the Products contained benzene, then Plaintiff and Class Members would not have purchased the Products.

#### **IX. Injuries to Plaintiff and Class Members**

90. When Plaintiff purchased Defendant's Products, Plaintiff did not know, and had no reason to know, that Defendant's Products contained or risked containing the harmful carcinogen benzene. Not only would Plaintiff not have purchased Defendant's Products had they known the Products contained benzene, but Plaintiff would also not have been capable of purchasing them if Defendant had done as the law required and tested the Products for benzene and other carcinogens and impurities, because the presence of benzene renders the Products adulterated, misbranded, and illegal to sell.

91. Consumers lack the ability to test or independently ascertain or verify whether a product contains unsafe substances, such as benzene, especially at the point of sale, and therefore must and rely on Defendant to report truthfully and honestly what the Products contain on the Products' packaging or labels.

92. Further, given Defendant's position as a retail industry leader, Plaintiff and

reasonable consumers, trusted and relied on Defendant's representations and omissions regarding the presence of benzene in the Products.

93. Yet, when consumers look at the Products' packaging, there is no mention of benzene. It is not listed in the ingredients section—which is where Defendant tells consumers to look to find out what is in the Products—nor is there any warning about the inclusion (or even potential inclusion) of benzene in the Products. This leads reasonable consumers to believe the Products do not contain benzene.

94. No reasonable consumer would have paid any amount for products containing benzene, a known carcinogen and reproductive toxin, much less above the limits set by the FDA (even assuming those allowances apply to Defendant's Products).

95. Thus, if Plaintiff and Class Members had been informed that Defendant's Products contained or may contain benzene, they would not have purchased or used the Products, or would have paid significantly less for the Products, making such omitted facts material to them.

96. Defendant's false, misleading, omissions, and deceptive misrepresentations regarding the presence of benzene in the Product are likely to continue to deceive and mislead reasonable consumers and the public, as it has already deceived and misled Plaintiff and Class Members.

97. Plaintiff and Class Members bargained for acne products free of contaminants and dangerous substances, and that were properly and legally sold. Plaintiff and Class Members were injured by the full purchase price of the Products because (i) the Products are worthless, as they are adulterated and contain harmful levels of benzene—or at risk of containing the same, and (ii) Plaintiff and Class Members would not have purchased the Products or would have paid substantially less for them had Defendant decided to not falsely represent that the Products did not

contain benzene.

98. As alleged above, Plaintiff and Class Members' Products either contained benzene or were at significant risk of containing the same.

99. Plaintiff and Class Members are further entitled to statutory and punitive damages, attorneys' fees and costs, and any further relief this Court deems just and proper.

### **CLASS ACTION ALLEGATIONS**

100. Plaintiff seeks to represent a class defined as all persons in the United States who purchased the Products for personal or household use within any applicable limitations period (the "Class").

101. Plaintiff also seeks to represent a subclass of all Class Members who purchased the Products for personal or household use in Illinois within any applicable limitations period (the "Illinois Subclass").

102. Plaintiff also seeks to represent a subclass of all Class Members who purchased the Products for personal or household use in California, Florida, Illinois, Massachusetts, Michigan, Minnesota, Missouri, New Jersey, New York, or Washington within any applicable limitations period (the "Consumer Fraud Multi-State Subclass").<sup>22</sup>

103. The Class and Subclasses are collectively referred to as the "Classes."

104. Subject to additional information obtained through further investigation and discovery, the foregoing definitions of the Classes may be expanded or narrowed by amendment to the complaint or narrowed at class certification.

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<sup>22</sup> While discovery may alter the following, the states in the Consumer Fraud Multi-State Class are limited to those states with similar consumer fraud laws under the facts of this case: California (Cal. Bus. & Prof. Code § 17200, et seq.); Florida (Fla. Stat. § 501.201, et seq.); Illinois (815 Ill. Comp. Stat. 505/1, et seq.); Massachusetts (Mass. Gen. Laws Ch. 93A, et seq.); Michigan (Mich. Comp. Laws § 445.901, et seq.); Minnesota (Minn. Stat. § 325F.67, et seq.); Missouri (Mo. Rev. Stat. § 407.010, et seq.); New Jersey (N.J. Stat. § 56:8-1, et seq.); New York (N.Y. Gen. Bus. Law §§ 349 and 350); and Washington (Wash. Rev. Code § 19.86.010, et seq.).

105. Specifically excluded from the Classes are Defendant, Defendant's officers, directors, agents, trustees, parents, children, corporations, trusts, representatives, employees, principals, servants, partners, joint ventures, or entities controlled by Defendant, and their heirs, successors, assigns, or other persons or entities related to or affiliated with Defendant and/or Defendant's officers and/or directors, the judge assigned to this action, and any member of the judge's immediate family.

106. **Numerosity.** The members of the proposed Classes are geographically dispersed throughout the United States and are so numerous that individual joinder is impracticable. Upon information and belief, Plaintiff reasonably estimates that there are hundreds of thousands of individuals that are members of the proposed Classes. Although the precise numbers of proposed members are unknown to Plaintiff, the true numbers of members of the Classes are known by Defendant. Members of the Classes may be notified of the pendency of this action by mail and/or publication through the distribution and sales records of Defendant and third-party retailers and vendors.

107. **Typicality.** The claims of the representative Plaintiff are typical of the claims of the Classes in that the representative Plaintiff, like all members of the Classes, purchased the Products, which were worthless due to the presence of benzene, a harmful and carcinogenic chemical impurity. The representative Plaintiff, like all members of the Classes, has been damaged by Defendant's misconduct in the very same way as the members of the Classes. Further, the factual bases of Defendant's misconduct are common to all members of the Classes and represent a common thread of misconduct resulting in injury to all members of the Classes.

108. **Existence and predominance of common questions of law and fact.** Common questions of law and fact exist as to all members of the Classes and predominate over any questions

affecting only individual members of the Classes. These common legal and factual questions include, but are not limited to, the following:

- (a) whether the Products contain benzene;
- (b) whether Defendant knew or should have known the Products contained benzene;
- (c) whether Defendant are liable to Plaintiff and the Classes for unjust enrichment;
- (d) whether Defendant failed to disclose that the Products contain benzene;
- (e) whether Defendant misrepresented whether the Products contain benzene;
- (f) whether Defendant violated the state consumer protection statutes alleged herein;
- (g) whether Plaintiff and the Classes have sustained monetary loss and the proper measure of that loss;
- (h) whether a reasonable consumer would consider the presence of benzene in the Products to be material;
- (i) whether the presence of benzene in the Products renders the Products adulterated or misbranded;
- (j) whether Plaintiff and the Classes are entitled to restitution and disgorgement from Defendant; and
- (k) whether the marketing, advertising, packaging, labeling, and other promotional materials for the Products are deceptive.

109. **Adequacy of Representation.** Plaintiff will fairly and adequately protect the interests of the Classes. Plaintiff has retained counsel who are highly experienced in complex



consumer class action litigation, and Plaintiff intends to vigorously prosecute this action on behalf of the Classes. Plaintiff has no interests that are antagonistic to those of the Classes.

110. **Superiority.** A class action is superior to all other available means for the fair and efficient adjudication of this controversy. The damages or other financial detriment suffered by members of the Classes are relatively small compared to the burden and expense of individual litigation of her claims against Defendant. It would, thus, be virtually impossible for members of the Classes, on an individual basis, to obtain effective redress for the wrongs committed against them. Furthermore, even if members of the Classes could afford such individualized litigation, the court system could not. Individualized litigation would create the danger of inconsistent or contradictory judgments arising from the same set of facts. Individualized litigation would also increase the delay and expense to all parties and the court system from the issues raised by this action. By contrast, the class action device provides the benefits of adjudication of these issues in a single proceeding, economies of scale, and comprehensive supervision by a single court, and presents no unusual management difficulties under the circumstances.

111. In the alternative, the Classes may be certified because:

- (a) the prosecution of separate actions by individual members of the Classes would create a risk of inconsistent or varying adjudication with respect to individual members of the Classes that would establish incompatible standards of conduct for the Defendant;
- (b) the prosecution of separate actions by individual members of the Classes would create a risk of adjudications with respect to them that would, as a practical matter, be dispositive of the interests of other members of the Classes not parties to the adjudications, or substantially impair or impede her ability to protect her interests; and/or
- (c) Defendant has acted or refused to act on grounds generally applicable to the Classes as a whole, thereby making appropriate final declaratory and/or injunctive relief with respect to the members of the Class as a whole.

**CAUSES OF ACTION**

**COUNT I**

**Violation of the Illinois Consumer Fraud and  
Deceptive Trade Practices Act 815 ILCS 505/1, *et seq.*  
(On Behalf of Plaintiff and the Illinois Subclass)**

112. Plaintiff incorporates by reference the allegations contained in the paragraphs above as if fully set forth herein.

113. Plaintiff brings this claim individually and on behalf of the members of the proposed Illinois Subclass against Defendant.

114. Plaintiff and other Illinois Subclass Members are persons within the context of the Illinois Consumer Fraud and Deceptive Trade Practices Act (“ICFA”), 815 ILCS 505/1(c).

115. Defendant is a person within the context of the ICFA, 815 ILCS 505/1(c).

116. At all times relevant hereto, Defendant was engaged in trade or commerce as defined under the ICFA, 815 ILCS 505/1(f).

117. Plaintiff and the proposed Illinois Subclass are “consumers” who purchased the Products for personal, family or household use within the meaning of the ICFA, 815 ILCS 505/1(e).

118. The ICFA does not apply to “[a]ctions or transactions specifically authorized by laws administered by any regulatory body or officer of this State or the United States.” 815 ILCS 505/10b(1).

119. The FDCA prohibits introduction into interstate commerce “of any food, drug, or cosmetic that is adulterated or misbranded.” 21 U.S.C. § 331(a).

120. As the Products are adulterated and misbranded, the FDCA specifically prohibits their introduction into interstate commerce, and thus, actions under the ICFA related to the Products being adulterated and misbranded are not barred by 815 ILCS 505/10b(1).

121. The ICFA prohibits engaging in any “unfair or deceptive acts or practices ... in the conduct of any trade or commerce.” ICFA, 815 ILCS 505/2.

122. The ICFA prohibits any deceptive, unlawful, unfair, or fraudulent business acts or practices including using deception, fraud, false pretenses, false promises, false advertising, misrepresentation, or the concealment, suppression, or omission of any material fact, or the use or employment of any practice described in Section 2 of the Uniform Deceptive Trade Practices Act (“UDTPA”). 815 ILCS § 505/2.

123. Plaintiff and the other Illinois Subclass Members reasonably relied upon Defendant’s representation that the Products were safe for personal use and, due to Defendant’s omission of the presence of benzene in the Products, Plaintiff read and relied on Defendant’s labeling to conclude that the Products were not contaminated with any dangerous substance, including benzene.

124. Defendant’s conduct, as described herein, took place within the State of Illinois and constitutes unfair or deceptive acts or practices in the course of trade and commerce, in violation of 815 ICFA 505/1, *et seq.*

125. Defendant engaged in unfair conduct in violation of the ICFA, including but not limited to selling misbranded products in violation of the FDCA and IL FDCA.

126. Defendant engaged in deceptive conduct, including but not limited to misrepresenting that the Products did not contain benzene, and failing to disclose that the Products contained benzene.

127. Defendant violated the ICFA by representing that the Products have characteristics or benefits that they do not have. 815 ILCS § 505/2; 815 ILCS § 510/2(7).

128. Defendant advertised the Products with intent not to sell them as advertised, in

violation of 815 ILCS § 505/2 and 815 ILCS § 510/2(9).

129. Defendant engaged in fraudulent and/or deceptive conduct which creates a likelihood of confusion or of misunderstanding in violation of 815 ILCS § 505/2; 815 ILCS § 510/2(3).

130. Prior to placing the Products into the stream of commerce and into the hands of consumers to use on their bodies, Defendant knew or should have known that the Products contained benzene, but Defendant not only failed to properly test and quality-check its Products, but further misrepresented, omitted, and concealed this fact to consumers, including Plaintiff and Illinois Subclass Members, by not including benzene or the risk of benzene contamination on the Products' labels or otherwise warning about its presence.

131. Defendant intended that Plaintiff and each of the other Illinois Subclass Members would reasonably rely upon the misrepresentations, misleading characterizations, warranties and material omissions concerning the true nature of the Products.

132. Given Defendant's position in the health, skin-care, and beauty market as an industry leader, Plaintiff and reasonable consumers trusted and relied on Defendant's representations and omissions regarding the presence of benzene in the Products.

133. Defendant's misrepresentations, concealment, omissions, and other deceptive conduct were likely to deceive and cause misunderstanding and/or in fact caused Plaintiff and each of the other Illinois Subclass Members to be deceived about the true nature of the Products.

134. Plaintiff and Illinois Subclass Members have been damaged as a proximate result of Defendant's unfair and deceptive violations of the ICFA and have suffered damages as a direct and proximate result of purchasing the Products.

135. As a direct and proximate result of Defendant's violations of the ICFA, as set forth

above, Plaintiff and the Illinois Subclass Members have suffered ascertainable losses of money caused by Defendant's unfair conduct of selling adulterated, misbranded, and illegally sold Products, and its misrepresentations and material omissions regarding the presence of benzene in the Products.

136. Had they been aware of the true nature of the Products, Plaintiff and the Illinois Subclass Members either would have paid less for the Products or would not have purchased them at all.

137. Based on Defendant's unfair and/or deceptive acts or practices, Plaintiff and the Illinois Subclass Members are therefore entitled to relief, including restitution, actual damages, treble damages, punitive damages, costs, and attorneys' fees, under 815 ILCS 505/10a.

**COUNT II**  
**Unjust Enrichment**  
**(On Behalf of Plaintiff and the Classes)**

138. Plaintiff incorporates by reference the allegations contained in the paragraphs above as if fully set forth herein.

139. Plaintiff brings this claim individually and on behalf of the members of the Classes against Defendant.

140. This claim is brought under the laws of the State of Illinois.

141. Plaintiff and the Classes conferred a benefit on Defendant in the form of monies paid to purchase Defendant's defective and worthless Products.

142. Defendant voluntarily accepted and retained this benefit.

143. Because this benefit was obtained unlawfully, namely by selling and accepting compensation for products unfit for human use, it would be unjust and inequitable for Defendant to retain the benefit without paying the value thereof.

**COUNT III**  
**Violation of State Consumer Fraud Acts**  
**(On Behalf of Plaintiff and the Consumer Fraud Multi-State Subclass)**

144. Plaintiff incorporates by reference the allegations contained in the paragraphs above as if fully set forth herein.

145. Plaintiff brings this claim individually and on behalf of the members of the Consumer Fraud Multi-State Subclass against Defendant.

146. The Consumer Fraud Acts of the States in the Consumer Fraud Multi-State Subclass prohibit the use of unfair or deceptive business practices in the conduct of trade or commerce.

147. Plaintiff and Consumer Fraud Multi-State Subclass Members have standing to pursue a cause of action for violation of the Consumer Fraud Acts of the states in the Consumer Fraud Multi-State Subclass because Plaintiff and Consumer Fraud Multi-State Subclass Members have suffered an injury in fact and lost money as a result of Defendant's actions set forth herein.

148. Defendant engaged in unfair conduct, including but not limited to selling adulterated and misbranded products in violation of the FDCA.

149. Defendant engaged in deceptive conduct, including but not limited to misrepresenting that the Products did not contain or did not risk containing benzene, and failing to disclose that the Products contained or risked containing benzene.

150. Defendant intended that Plaintiff and Consumer Fraud Multi-State Subclass Members would rely upon its unfair and deceptive conduct and a reasonable person would in fact be misled by this deceptive conduct described above.

151. Given Defendant's position in the health and beauty market as an industry leader, Plaintiff and reasonable consumers trusted and relied on Defendant's representations and

omissions regarding the presence of benzene in the Products.

152. As a result of Defendant's use or employment of unfair or deceptive acts or business practices, Plaintiff and Consumer Fraud Multi-State Subclass Members have sustained damages in an amount to be proven at trial.

153. In addition, Defendant's conduct showed malice, motive, and the reckless disregard of the truth such that an award of punitive damages is appropriate.

### **PRAYER FOR RELIEF**

WHEREFORE, Plaintiff respectfully requests, individually and on behalf of the alleged Classes, that the Court enter judgment in her favor and against Defendant as follows:

- (a) For an order certifying the Classes under Rule 23 of the Federal Rules of Civil Procedure, naming Plaintiff as the representative for the Classes, and naming Plaintiff's attorneys as Class Counsel to represent the Classes;
- (b) For an order declaring that Defendant's conduct violates the causes of action referenced herein;
- (c) For an order finding in favor of Plaintiff and the Classes on all counts asserted herein;
- (d) For compensatory, statutory, and punitive damages in amounts to be determined by the Court and/or jury;
- (e) Awarding pre-judgment and post-judgment interest;
- (f) For an order of restitution and all other forms of equitable monetary relief;
- (g) For injunctive relief as pleaded or as the Court may deem proper; and
- (h) For an order awarding Plaintiff and the Classes her reasonable attorneys' fees and

expenses and costs of suit.

**DEMAND FOR JURY TRIAL**

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiff demands a trial by jury of any and all issues in this action so triable as of right.

Dated: April 5, 2024

Respectfully submitted,

/s/ Gary M. Klinger

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